K130109

510(k) Summary or 510(k) Statement

510 (k) Summary

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Number:

Submitter:
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ITALY
Registration # 8021091

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AUG 0 1 2013

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Date Prepared: July 12, 2013

Trade Name: Endograph DC

Common Name: Extra oral source X-ray unit

Classification Name: 872.1800 Unit, x-ray, extraoral with timer

Class: II

Product Code: EHD

Predicate Device: The Endograph DC is compared with the following predicate device:

- ViVi S.r.l. Ergon-X HF (K120318),

Product Description: Endograph DC is an extraoral source x-ray unit.
Endograph DC is dedicated to intraoral radiography in which the x-ray source is placed outside the mouth of the patient while the image detector (film or digital detector) is placed inside the mouth.
The image detector is not part of Endograph DC system, so it is not part of this submission.

Indication for Use: Endograph DC is an extraoral source x-ray unit for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device is to be operated and used by

dentists, radiologists and other legally qualified health care professionals. It can be used with both pediatric and adult patients.

Rationale for Substantial Equivalence:

Endograph DC has the same indication for use as the predicate device. It shares the same technological characteristics as the predicate device. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device.

Safety and Effectiveness Information:

The device labeling contains operating instructions for safe and effective use of Endograph DC. The software development for this device follows documented processes for software design, verification and validation testing. Final device validation and risk assessment has been conducted, to identify potential design hazards that could cause an error or injury based on the use of this device. Appropriate steps have been taken to control all identified risks. The device has been tested for compliance to IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety. and its derivatives

Conclusion:

Endograph DC performs the same functions in the same environment as the predicate device. It shares the same technology as the predicate device. It is based on well known technology. It is as safe and effective as the predicate device. We believe it does not introduce any new potential safety risks and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 1, 2013

Villa Sistemi Medicali, S.p.a.
% Mr. Paolo Casagrande Santin
Via Delle Azalee, 3
20090 Buccinasco (MI)
ITALY

Re: K130109
Trade/Device Name: Endograph DC
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: July 12, 2013
Received: July 24, 2013

Dear Mr. Santin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

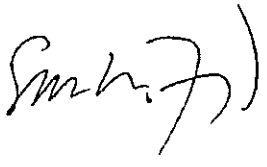
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130109

Device Name: **Endograph DC**

Indications for Use:

Endograph DC is an extraoral source x-ray unit for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device is to be operated and used by dentists, radiologists and other legally qualified health care professionals. It can be used with both pediatric and adult patients.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130109